BRITISH STANDARD

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Dentistry — Medical devices for dentistry — Materials

The European Standard EN 1641:2004 has the status of a British Standard

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National foreword

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The UK participation in its preparation was entrusted by Technical Committee CH/106, Dentistry, to Subcommittee CH/106/2, Prosthodontic materials, which has the responsibility to:

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Contents

Foreword

This document (EN 1641:2004) has been prepared by Technical Committee CEN/TC 55 “Dentistry”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document supersedes EN 1641:1996.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC..

For relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

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Introduction

There are three levels of European Standards dealing with medical devices used in dentistry. These are as follows:

— Level 1: General requirements for medical devices;

— Level 2: Particular requirements for families of medical devices used in dentistry;

— Level 3: Specific requirements for types of medical devices used in dentistry.

There are no level 1 standards written exclusively in respect of medical devices used in dentistry.

This standard is a level 2 standard and details requirements that apply to those materials used in the practice of dentistry for the restoration of the form and function of the dentition (for dental implants see EN 1642). It is also indicated that there are additional requirements in the level 3 standards. Where available, these are included as normative references. To cover all the requirements for a particular product, it is necessary to use a standard of the lowest available level.

The manufacturer will need to consider whether:

1) The material incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EEC [2], and whose action in combination with the material can result in its bioavailability. Directive 2001/83/EEC specifies the appropriate methods for assessing the safety, quality and usefulness of that substance.

2) The material includes a constituent which may be classified as a hazardous substance according to the Dangerous Substances Directive 67/548/EEC [3], as amended by the Dangerous Preparations Directive 1999/45/EC [4]. Attention is drawn to the labelling requirements of these Directives where the hazardous constituent content is above certain concentration limits.

In the Bibliography a reference for guidance on the classification of dental devices and accessories [5] is given.

1 Scope

This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. For the purposes of this standard these materials are defined as restorative materials. Dental implants are specifically excluded and described in EN 1642. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 21560, *Dentistry — Dental mercury.*

EN 21563, *Alginate dental impression material (ISO 1563:1990).*

EN 21942-1, *Dental vocabulary — Part 1: General and clinical terms.*

EN 21942-2, *Dental vocabulary — Part 2: Dental materials (ISO 1942-2:1989).*

EN 23107, *Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements (ISO 3107:1988).*

EN 26874, *Dental resin-based pit and fissure sealants (ISO 6874:1988).*

EN 28601, *Data elements and interchange formats — Information interchange — Representation of dates and times (ISO 8601:1988 and its technical corrigendum 1:1991).*

EN 29333, *Dental brazing materials (ISO 9333:1990).*

EN 30139-1, *Dentistry — Resilient lining materials removable dentures — Part 1: Short-term materials (ISO 10139-1:1991).*

EN ISO 1559, *Dental materials - Alloys for dental amalgam (ISO 1559:1995 + Technical Corrigendum 1:1997)*

EN ISO 1561, *Dental casting wax (ISO 1561:1995).*

EN ISO 1562, *Dental casting gold alloys (ISO 1562:1993).*

EN ISO 1564, *Dental aqueous impression materials based on agar (ISO 1564:1995).*

EN ISO 1567, *Dentistry — Denture base polymers (ISO 1567:1999).*

EN ISO 1942-5, *Dental vocabulary — Part 5: Terms associated with testing (ISO 1942-5:1989).*

EN ISO 3336, *Dentistry — Synthetic polymer teeth (ISO 3336:1993).*

EN ISO 4049, *Dentistry — Polymer-based filling, restorative and luting materials (ISO 4049:2000).*

EN ISO 4823, *Dentistry — Elastomeric impression materials (ISO 4823:2000)*

EN ISO 4824, *Dentistry — Ceramic denture teeth (ISO 4824:1993).*

EN ISO 6871-1, *Dental base metal casting alloys — Part 1: Cobalt-based alloys (ISO 6871-1:1994).*

EN ISO 6872, *Dental ceramic (ISO 6872:1995).*

EN ISO 6873, *Dental gypsum products (ISO 6873:1998).*

EN ISO 6876, *Dental root canal sealing materials (ISO 6876:2001)*

EN ISO 6877, *Dental root-canal obturating points (ISO 6877:1995).*

EN ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials (ISO 7405:1997).*

EN ISO 7491, *Dental materials — Determination of colour stability (ISO 7491:2000).*

EN ISO 7551, *Dental absorbent points (ISO 7551:1996).*

EN ISO 8891, *Dental casting alloys with noble metal content of at least 25 % but less than 75 % (ISO 8891:1998).*

EN ISO 9693, *Metal-ceramic dental restorative systems (ISO 9693:1999).*

EN ISO 9917-2, *Dental water-based cements — Part 2: Light activated cements (ISO 9917-2:1998).*

EN ISO 10139-2, *Dentistry — Soft lining materials for removable dentures — Part 2: Materials for long-term use (ISO 10139-2:1999).*

EN ISO 10271, *Dental metallic materials — Corrosion test methods (ISO 10271:2001).*

EN ISO 10477, *Dentistry — Polymer-based crown and bridge materials (ISO 10477:1992).*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003).*

EN ISO 12163, *Dental baseplate/modelling wax (ISO 12163:1999).*

EN ISO 13716, *Dentistry — Reversible-irreversible hydrocolloid impression material systems (ISO 13716:1999).*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003).*

EN ISO 14155-2, *Clinical investigations of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003).*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 21942-1, EN 21942-2, EN ISO 1942-5 and the following apply.

3.1
restorative material
material used in restorative dentistry including, for example, impression and other materials used transiently in the mouth, denture teeth and denture base resins, casting alloys, filling and lining materials

4 Requirements

4.1 General

4.1.1 Restorative materials shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the device concerned. Conformity with these requirements shall be considered to be met by demonstrating compliance with the requirements of the following subclauses, if appropriate.

4.1.2 A risk analysis shall be carried out and documented.

NOTE EN ISO 14971 [6] describes the procedures to be carried out.

4.2 Chemical and physical properties

4.2.1 Composition

Restorative materials shall satisfy the compositional requirements as specified in the following standards, if appropriate:

EN 21560, EN 23107, EN 29333, EN ISO 1559, EN ISO 1562, EN ISO 1567, EN ISO 4824, EN ISO 6871-1, EN ISO 6872, EN ISO 8891, EN ISO 9693, EN ISO 9917-2.

4.2.2 Biocompatibility

Restorative materials shall be assessed for biocompatibility. Guidance on the selection of tests is given in EN ISO 7405 and EN ISO 10993-1. EN ISO 7405 includes usage tests specific to dental materials.

4.2.3 Material properties

The chemical and physical properties of restorative materials shall be determined in accordance with the test methods as specified in the following standards, if appropriate:

EN 21560, EN 21563, EN 23107, EN 26874, EN ISO 6876, EN 29333, EN 30139-1, EN ISO 1559,.EN ISO 1561, EN ISO 1562, EN ISO 1564, EN ISO 1567, EN ISO 3336, EN ISO 4049, EN ISO 4823, EN ISO 4824, EN ISO 6871-1, EN ISO 6872, EN ISO 6873, EN ISO 6877, EN ISO 7491, EN ISO 7551, EN ISO 8891, EN ISO 9693, EN ISO 9917-2, EN ISO 10139-2, EN ISO 10271, EN ISO 10477, EN ISO 12163, EN ISO 13716.

4.3 Control of contamination

4.3.1 Restorative materials shall be designed and manufactured under conditions to minimize microbial or other contamination, if appropriate.

4.3.2 Packaging systems for restorative materials supplied non-sterile shall maintain the level of cleanliness of the materials during transport and storage.

4.4 Restorative materials used in combination

Restorative materials intended for use in combination shall meet the requirements as specified in the following standards, if appropriate:

EN 21560, EN 21563, EN 29333, EN 30139-1, EN ISO 1559, EN ISO 1562, EN ISO 1564, EN ISO 1567, EN ISO 3336, EN ISO 4823, EN ISO 4824, EN ISO 6871-1, EN ISO 6872, EN ISO 6873, EN ISO 6877, EN ISO 8891, EN ISO 9693, EN ISO 9917-2, EN ISO 10271, EN ISO 10139-2, EN ISO 10477.

4.5 Clinical investigation

Clinical investigation of restorative materials, if appropriate, shall be conducted in accordance with EN ISO 14155-1 and EN ISO 14155-2.

4.6 Marking, labelling and information supplied by the manufacturer

4.6.1 General

Information required for the safe use of restorative materials shall be provided by the manufacturer in accordance with EN 980, EN 1041, relevant product standards and 4.6.2, 4.6.3 and 4.6.4.

4.6.2 Symbols

Marking, labelling and instructions for use of restorative materials shall, if appropriate, include information in the form of symbols as specified in the following standards:

EN 980, EN 21560.

4.6.3 Labelling

4.6.3.1 The label shall include the following minimum information:

a) Name or registered trade mark and address of the manufacturer. In the case of imported restorative materials the name and address of the authorised representative of the manufacturer in the EU;

b) Description of the contents, including name, quantity, form (e.g. powder, liquid, paste), shade where appropriate, and the principal chemical constituents in order to identify the type of material;

c) Batch code, preceded by the word "LOT" or the symbol LOT, or the serial number preceded by SN, related to the records of raw materials, manufacture and packaging;

d) "use by" date expressed in accordance with EN 28601, if appropriate;

e) The words "exclusively for clinical investigation", if the restorative material is intended for clinical investigations;

f) Special storage and/or handling conditions;

g) Warnings and/or precautions to take.

4.6.3.2 If it is not practicable for all the above information to be included on the label of the primary container, the relevant information shall be provided on the outer packaging or included in the instructions for use.

4.6.4 Instructions for use

The instructions for use shall include the following minimum information:

a) Details referred to in 4.6.3.1 with the exception of c) and d);

b) Intended purpose of the restorative material;

c) Constituents which may give rise to undesirable side effects;

d) Sufficient details of its characteristics to identify the correct equipment and procedures to be used in order to obtain a safe combination if the restorative material is intended to be used in combination with other restorative materials or devices;

e) Information to avoid risks in connection with the use of the restorative material, if appropriate;

f) Details of any further treatment or handling needed for the proper use of the restorative material. These should include, if applicable, details of application, method of preparation, proportioning, mixing or trituration, working time, setting time, recommended fusion, casting or curing procedures and method of finishing;

g) Information on the environmental conditions which may adversely effect the materials such as temperature, humidity or ambient light, and the disposal of waste, if precautions are necessary;

h) If applicable, details allowing the dental personnel to brief the patient on the precautions to be taken. These details shall including in particular:

1) Precautions to be taken in the event of changes in the performance of the restorative material;

2) Information on the risks to the patient that may arise after placement;

3) Adequate information if the restorative material contains a medicinal product;

4) Adequate information, if appropriate, for the care of finished restorations.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC concerning medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1 – 6	
4.2.1	7.1, 7.2	
4.2.2	7.1	
4.2.3	7.1	
4.3.1	7.2, 8.1	
4.3.2	8.6	
4.3	7.3	
4.4	9.1	
4.5	14	
4.6.1	13.1	
4.6.2	13.2	
4.6.3	13.3	
4.6.4	13.6	

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

[1] 93/42/EEC Council Directive of 14 June 1993 concerning medical devices (O.J. L. 169 from 12.07.1993, page 1-43).

[2] 2001/83/EC of the European Parliament and the Council of 6 November 2001 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to human drugs (O.J. L. 311 from 28.11.2001, page 67).

[3] 67/548/EEC Council Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[4] 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

[5] CEN/TR 12401:2003, *Dentistry — Guidance on the classification of dental devices and accessories.*

[6] EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000).*

[7] EN 1642, *Dentistry — Medical devices for dentistry — Dental implants.*

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